

REMARKS

In the subject Office Action dated December 6, 2006, claims 1, 3-11, 13, 15-20 and 22 were examined. In response thereto, claims 1, 4, 7, 8, 13, 20 and 22 are amended, and claims 3, 5, 6, 9-11 and 15-19 remain under active prosecution. Applicants assert that the amendments are subject in the originally filed application and do not introduce new subject matter. Moreover, Applicants assert that these amendments present no new issues and should be admissible after final rejection.

Applicants appreciate the courtesies extended during the telephonic interview on March 26, 2007 (hereinafter "Interview"). While no agreement was reached during the Interview, the Examiner did express appreciation of the differences in amended claim 1 and would reconsider amended claim 1. Likewise, amended claim 13 was also discussed with the same results. The Applicants would like the Examiner to carefully consider the above amended claims presented in light of our discussions

Claim Rejections - 35 USC §112

The Examiner has rejected claim 22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated that claim 22 recites the limitation "the ring" in line 1. The Examiner has also noted that the recitation of an anastomosis ring in claim 1 is a functional limitation, and thus is not positively claimed and is not proper antecedent basis.

In response to the Examiner's rejection of claims 22 and 1 under 35 U.S.C. 112, second paragraph, the Applicants have amended claim 22 to recite "a ring" in line 1 and have also amended claim 1 to provide proper antecedent basis for the anastomosis ring device. Applicants believe that the amendments to claims 1 and 22 move them away from the Examiner's rejections, and that claims 1 and 22 are now in position for allowance with respect to the 35 U.S.C. 112, second paragraph rejections.

Claim Rejections - 35 USC § 102

The Examiner has rejected claim 13 rejected under 35 U.S.C. 102(e) as being anticipated by Suyker (US 6,485,496). The examiner has stated that regarding Claim 13, Suyker teaches a surgical instrument, comprising: a cannula (58); an actuating member (59) distally and laterally presented on the cannula for receiving a generally cylindrical anastomosis ring (1) and formed of radially spaced proximal leaves (61) which each distal leaf outwardly actuates by a cantilevered, hinged relationship to a central portion of the actuating member (59); a first control (proximal end of cannula 58) operative to compress a longitudinal end of the actuating member toward a center of the actuating member to actuate a respective portion of the received anastomosis ring; a second control (proximal end of shank 13) to compress another longitudinal end (60) of the actuating member toward the center of the actuating member to actuate the other respective portion of the received anastomosis ring forming a hollow rivet shape (Column 8, proximal lines 57-64); wherein the first and second controls are capable of being independently actuatable to allow independent actuation of either longitudinal end of the actuating member.

Applicants submit that Suyker fails to teach or suggest all of the limitations recited in amended independent claim 13, particularly in the arrangement required by amended claim 13. For instance, amended independent claim 13 recites a nonexpanding central portion. Suyker fails to teach or suggest such limitations, among others, particularly in the arrangement as required by amended claim 1. Accordingly, Suyker fails to anticipate claim 1 in accordance with MPEP 2131. Applicants further note that the dependent claims include additional limitations not taught or suggested in the art of record, thus forming independent basis for novelty, and that the rejection of dependent claims rejected under U.S.C. 102(e) in light of Slocum is not anticipated. Applicants therefore respectfully request that the rejection be withdrawn for independent claim 1 as well as claims that depend therefrom.

The Examiner has also rejected dependent claim 15 under Suyker stating that Suyker teaches the surgical instrument of claim 13 further comprises a stationary member (57) mechanically grounding the center of the actuating member relative to the first cannula. For the reasons given above for amended claim 13, reconsideration and allowance of claim 15 is respectfully requested.

Claim Rejections - 35 USC § 103

The Examiner has rejected claim 1 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as an obvious matter of design choice. The Examiner stated that regarding Claim 1, Suyker (see embodiment of Figs. 37-40) teaches a surgical instrument capable of implanting an anastomotic ring device comprising a woven tube of wire having outer loops or ends which thermally deform and evert when inserted into walls of two adjacent lumens at a luminal interface of an anastomotic site, the ends of the tube everting to form petals in a manner which holds the luminal interface of the anastomotic site into apposition, comprising: an actuating member (14) formed of a plurality of proximal leaves (61) and a plurality of distal leaves (61, see fig. 38) which each leaf outwardly actuate by a cantilevered hinged relationship to a central portion (59, 60) of the actuating member, configured to receive an anastomotic ring (1) and moveable between a cylindrical, unactuated position (Fig. 7) and a hollow rivet forming shape (Fig. 11) in response to a compressive actuating force; a plurality of distal engaging surfaces (ends of petals 61 not connected to cannula) each formed on a respective distal leaf spaced away from the central portion and positioned to engage a selected outer loop of a distal portion of the unactuated, cylindrical anastomotic ring for pulling the engaged outer loop proximally and outwardly during actuation; a plurality of proximal engaging surfaces (ends of petals 61 not connected to cannula) each formed on a respective proximal leaf spaced away from the central portion and positioned to engage a selected outer loop of a proximal portion of the unactuated, cylindrical anastomotic ring for pulling the engaged outer loop distally and outwardly during actuation; a handle including an actuation mechanism for producing the compressive actuating force (Column 5, proximate lines 15-19, it is noted that although a handle is not explicitly recited for the embodiment of Figs. 37-40, it is inherent that a handle connected to the shank and the sleeve is present to actuate the device, otherwise it would be obvious to one of ordinary skill in the art at the time the invention was made to provide a handle for actuating the device since it is well known in the art to provide a handle on the non-working end of a device for actuation); an elongate cannula (58) configured to position the distal leaves on a distal side of an anastomotic opening and to position the proximal leaves on a proximal side of the anastomotic opening, and configured to transfer the compressive actuating force from the handle to the actuating member wherein the handle is further operably configured to produce

the compressive actuating force by producing a proximally directed longitudinal motion and a distally directed longitudinal motion (Fig. 37 to Fig. 38), the device operably configured to separately transfer the proximally and distally directed longitudinal motions respectively to distal and proximal portions of the actuating member to pivot corresponding distal and proximal leaves toward each other to actuate the anastomotic ring device from a cylinder shape to a hollow rivet shape (Column 8, proximal lines 57-64).

With respect to claim 1, during the Interview, the differences between amended claim 1 and the art of Slocum were discussed. Applicant submit that the art of record fails to teach or suggest all of the limitations recited in the claim in accordance with MPEP 2143.03. For instance, Applicants note that amended claim 1 recites “expandable proximal leaves and a plurality of expandable distal leaves with each leaf outwardly actuate by a cantilevered, hinged relationship to a nonexpanding central portion of the actuating member”. These limitations, among others recited in amended claim 1, are neither taught nor suggested by the combined art of record. Applicants therefore submit that the combined art of record fails to teach or suggest all of the limitations of amended claim 1 in accordance with MPEP 2143.03. Accordingly, Applicants respectfully submit that the combined art of record fails to render present claim 1 obvious in accordance with MPEP 2143, and respectfully requests that the rejection be withdrawn.

The Examiner has also rejected dependent claim 3 is under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Kim (US 5797920). The Examiner stated that Suyker teaches all limitations of claim 1, and further teaches wherein the cannula comprises a first tube (58) connected to the proximal portion of the actuating member (59), and a second member (13) slidably received in the tube and connected to the distal portion of the actuating member (60) and that Suyker fails to teach wherein the second member is a tube. Kim teaches an anastomosis device wherein the inner member connected to the distal actuating member (124) is a tube in order to insert tools for controllably expanding or contracting the size of the distal end of the device.

With respect to claim 3 which depends from amended claim 1, the Applicants submit that for the reasons given above for amended claim 1, the art of record fails to teach or suggest all of the limitations recited in dependent claim 3 in accordance with MPEP 2143.03. Applicants respectfully request reconsideration and allowance of claim 3.

The Examiner has also rejected claims 5, 6 and 16 under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Kim (US 5797920). The Examiner stated that Suyker teaches all limitations of preceding dependent claims 1 and 13, but fails to teach wherein the device comprises an enterotomy creation tip distally coupled to the actuating member. Kim teaches wherein the distal end of the device comprises an enterotomy creation piercing tip (130) in order to create an insertion opening for the anastomosis ring and deploy the ring with the same device.

With respect to dependent claims 5, 6, the Applicants once again submit that for the reasons given above for amended claim 1, the art of record fails to teach or suggest all of the limitations recited in dependent claims 5 and 6 in accordance with MPEP 2143.03. For the reasons above, reconsideration and allowance of claims 5 and 6 is respectfully requested.

With respect to claim 16 which depends from amended claim 13, Applicants submit that the art of record fails to teach or suggest all of the limitations recited in the claim in accordance with MPEP 2143.03. For instance, Applicants note that amended independent claim 13 recites “the actuating member formed of a plurality of radially spaced proximal leaves and a plurality of radially spaced distal leaves with each leaf outwardly expanded by a cantilevered, hinged relationship to a nonexpanding central portion of the actuating member;”. These limitations, among others recited in claim 16, are neither taught nor suggested by the combined art of record. Applicants therefore submit that the combined art of record fails to teach or suggest all of the limitations of claim 16 in accordance with MPEP 2143.03. Accordingly, Applicants respectfully submit that the combined art of record fails to render present claim 16 obvious in accordance with MPEP 2143, and respectfully requests that the rejection be withdrawn, and allowance of claim 16 is respectfully requested.

Claims 11, 17, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Suyker and Kim and further in view of Yeatman (US 6,451,029) and further as a matter of design choice. The Examiner also stated the combination of Suyker and Kim teaches all aspects of preceding dependent claims 1, 5, 6 and 13 as previously described, but fails to disclose wherein the instrument comprises a pneumatic conduit communicating between the distal tip and the handle for inflating a body lumen, and the tip comprising a veress needle. Yeatman teaches an intestinal stapling device wherein a pneumatic conduit (26) is in communication with the distal tip and handle (30) in order to provide a means of

leak testing and performing anastomosis with a common instrument. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Suyker and Kim with a pneumatic conduit communicating between the distal tip and the handle for inflating a body lumen as taught by Yeatman in order to provide a means of leak testing and performing anastomosis with a common instrument. Regarding the limitation wherein the piercing tip comprises a veress needle, it is noted that a veress needle is one that serves to insufflate a body cavity for a laparoscopic procedure. It is further noted that the combination of Suyker, Kim and Yeatman as described above fulfills that description, and therefore fulfills the structure and function of a veress needle.

With respect to dependent claim 11, Applicants submit that for the reasons given above for amended claim 1, the art of record fails to teach or suggest all of the limitations recited in dependent claim 11 in accordance with MPEP 2143.03, and reconsideration and allowance of claim 11 is respectfully requested.

Claims 17, 18 and 19 depend from amended claim 13 and the Applicants submit that for the reasons given above for amended claim 13, the art of record fails to teach or suggest all of the limitations recited in claims 17, 18, and 19 in accordance with MPEP 2143.03, and reconsideration and allowance of claims 17, 18, and 19 is also respectfully requested.

The Examiner has also rejected claim 7 under 35 U.S.C. 103(a) as being unpatentable over the combination of Suyker and Kim as applied to claim 6 above, and further in view of Kulkashi et al. (US 5,098,388). The combination of Suyker and Kim teaches all limitations of preceding dependent claims 1 and 6 as previously described, but fails to teach wherein the piercing tip comprises a veress needle having a syringe knife tip within which a ball translates and springedly withdraws into the veress needle to expose the piercing surfaces. Kulkashi teaches a veress needle having a syringe knife tip in which a ball translates and springedly withdraws into the veress needle in order to provide a piercing tip that minimizes the risk of contaminants being carried by gas into the abdominal cavity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Suyker and Kim with a syringe knife tip in which a ball translates and springedly withdraws into the veress needle as taught by Kulkashi in order to provide a piercing tip that minimizes the risk of contaminants being carried by gas into the abdominal cavity.

With respect to claim 7 which depends from claim 1, once again the Applicants submit that for the reasons given above for amended claim 1, the art of record fails to teach or suggest all of the limitations recited in dependent claim 7 in accordance with MPEP 2143.03, and reconsideration is respectfully requested. Applicants have also amended claim 7 to correct a spelling error and have changed “spingedly” to “springedly”. Support for the change is supported within the specification, and no new matter was added.

The Examiner has also rejected Claim 22 under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Park et al. (US 2003/0032967). Suyker teaches all limitations of preceding dependent claim 1 as previously described, but fails to teach wherein the anastomosis ring comprises a woven tube of wire having outer loops or ends which thermally deform and evert when inserted into walls of two adjacent lumens at a luminal interface of an anastomotic site, the ends of the tube everting to form petals in a manner which holds the luminal interface of the anastomotic site into apposition. Park teaches an anastomosis ring (10) comprising a woven tube of wire (18) having outer loops or ends (20') which thermally deform and evert when inserted into walls of two adjacent lumens at a luminal interface of an anastomotic site (Fig. 1), the ends of the tube everting to form petals in a manner which holds the luminal interface of the anastomotic site into apposition (Fig. 4) in order to reduce the need for mechanical compression of the anastomosis ring. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Suyker with the anastomosis ring of Park in order to reduce the need for mechanical compression of the anastomosis ring.

Again, with respect to claim 22 which depends from amended claim 1, once again the Applicants submit that for the reasons given above for amended claim 1, the art of record fails to teach or suggest all of the limitations recited in dependent claim 22 in accordance with MPEP 2143.03, and reconsideration and allowance is respectfully requested.

Allowable Subject Matter

Applicants would like to thank the Examiner for indicating that claims 4, 8, 9, 10 and 20 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants have amended rewritten claims 4, 8, and 20 to include all of the limitations of the previously presented base claims. Claims 9 and 10

Serial No. 10/675,497

depend from rewritten amended claim 8 and do not require rewriting . Consequently, claims 4, 8, 9, 10 and 20 stand ready for allowance.

Conclusion

In light of the remarks made herein, it is respectfully submitted that the claims currently pending in the present application are in form for allowance. Accordingly, reconsideration of those claims, as amended herein, is earnestly solicited. If there are any additional matters which may be resolved by telephone or fax, Applicants encourage the Examiner to contact their representative, David E. Franklin at (513) 651-6856 or dfranklin@fbtlaw.com to expedite issuance of this application.

Because the application previously contained 18 claims with 3 independent claims and now contains, after amendment, 18 claims with 5 independent claims, claim fees \$400 are due and may be charged to the firm charge account. An extension of time of one month is requested and the fee for the one month extension may be charged to the firm charge account. In addition, if necessary, the Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

CERTIFICATE OF MAILING

I hereby certify that a copy of this correspondence is being deposited with the US Patent Office by electronic transmission addressed to MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 5, 2007.

Elizabeth A. Middleton

Elizabeth A. Middleton

Respectfully submitted,

Mark S. Ortiz, et. al.

By *David E. Franklin*

David E. Franklin
Registration No. 39,194
Attorney for Applicant(s)
FROST BROWN TODD LLC
2200 PNC Center
201 East Fifth Street
Cincinnati, Ohio 45202
(513) 651-6856
dfranklin@fbtlaw.com